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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/583,835

06/19/2006

Rolf Muller

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EXAMINER

ANDERSON, JERRY W

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/583,835	<b>Applicant(s)</b> MULLER ET AL.	
	<b>Examiner</b> JERRY W. ANDERSON	<b>Art Unit</b> 1781	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2,4,7-16 and 18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2,4,7-16 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/19/10</u>  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Examiner acknowledges the receipt of the Applicant's Amendment, mailed 11/18/10. Claims 1, 3, 5, 6, & 17 cancelled, claims 18 new, and claims 2, 4, 7-16, & 18, pending.

#### ***Claim Objections***

2. Claim 18 objected to because of the following informalities: the use of a trademark Megazyme in claim 18 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

3. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1781

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 18 is rejected under 35 U.S.C. 112, first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. The use of trademarks (Megazyme) in claim 18 without any description in the specification is indefinite. Trademarks describe products that are subject to change at the pleasure of their manufacturers and are therefore indefinite in the claims unless accompanied by the generic terminology. It is however, preferred that generic terminology be used in the claims to more distinctly claim applicant's subject matter.

When generic terminology is supplied to the specification and claims, it should be accompanied by some literature or prior art that supports such terminology. mpep

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Art Unit: 1781

8. Claim 18 contains a reference to AOAC method 2002.02 wherein said reference is a limitation of the claim, in that the initial hydrolysis rate (Ho) of the finished foodstuff is measured based upon an AOAC method 2002.02. By referring to a method published by the Journal of AOAC, a standard method of analysis of resistant starch, this renders the claim indefinite, since the scope of the method is not clearly defined. The specification does not clearly define the term, nor does the claim. Thus the claim is indefinite.

9. Further, although the AOAC method is published as a standard method, the method was adopted in 2002, and may change in the future, to reflect advances in analytical procedures or other factors as yet unknown. For a comparison of the different analyses methods for dietary fiber, and problems in the analysis of dietary fiber. see Brunt.

10. Claims 2, 4, and 7-16, being dependent upon claim 18, are likewise, rejected.

### ***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1781

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. **Claims 18, 2, 4, 7, and 11-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Y-C. Shi. (6,890,571)**

14. Regarding the limitations added by amendment, these are product by process claims; the determination of patentability in a product-by-process claim is based on the product itself, even though the claim may be limited and defined by the process. That is, the product in such a claim is unpatentable if it is the same as or obvious from the product of the prior art, even if the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985). A product-by-process limitation adds no patentable distinction to the claim, and is unpatentable if the claimed product is the same as a product of the prior art.

15. **Regarding Claims 18 and 17**, the Applicant claims a slow digestible starch, partially gelatinized, with a DSC melting point is >60 deg C, and initial hydrolysis rate (Ho) is reduced by > 10 %, and 3-60% Short chain amylose relative to the entire starch, , Shi teaches a resistant, gelatinized starch, (lines 6-9 col. 3, lines 46-48 col. 4, '571, ) a starch that is resistant to digestion in the small intestine, and passes into the large intestine, ( line 13-15 col. 1 '571) a DSC melting point of at least about 90 deg. C (line

Art Unit: 1781

50-53 col. 4 '572), and digestibility being reduced to less than 50 % in two hours,. (lines 5-14 col. 1 '571)

16. Further, Shi discloses that the reaction is continued until a slowly digestible starch is achieved, up to 24 hours, (lines 31-33, col. 3, '571) and the short chain amylase content is about 98 % (line 44-48 col. 3 '571) and is highly crystalline short chain amylose, (lines 46-28 col. 4 '571) optionally the enzyme may be deactivated. (lines 51, col. 3, '571) The debranched starch may be characterized by the dextrose equivalent (DE), the reducing power of the hydrolysate, anhydrous glucose is 100 and unhydrolyzed starch is zero.

17. As to the measurement of the hydrolysis rate, the aforesaid product by process argument above is restated, including the process for the measurement of the resistant starch does not lend patentable weight to the product, if the product is the same or obvious from the product of the prior art. However, Shi does use the Megazyme kit. (lines 17-21, col. 7, '571) Further, Shi refers to a method for the analysis of resistant starch, Englyst, H. N. et al., which distinguishes between the types of slowly digestible starch and resistant starch, as does the AOAC method 2002.02. (Englyst, Brunt) Brunt is provided solely to show the similarity in the measurement of resistant starch of the methods of Englyst, and the AOAC method.

18. Regarding the amount of short chain amylase in samples 1A-1D, Shi discloses that for 1A the reaction was stopped at DE 6.0, 1B after 8 hours, 1C after 16 hours, and 1D at DE 5.3. (lines 53, col.7 -lines29, col. 8, '571) The data in table 1 shows that 1A and 1C are similar as is 1B and 1D, and since 1B and 1D are characterized by having a

Art Unit: 1781

shorter reaction time and reacting to a less DE value, one of ordinary skill in the art would conclude that the amount of short chain amylose produced was likewise lower. Considering the below discussion, one of ordinary skill in the art would find it obvious that if Shi's starch products have the same characteristics as the instant applications then, logically it follows that the composition must be similar. From the standpoint of patent law, a compound and all of its properties are inseparable. (In re Papesch, 315 F.2d 381, 137 USPQ 43, 51 CCPA 1963)

19. It would be obvious to one of ordinary skill in the art that the instant invention, samples WS-57 1-4 and Shi's data from sample set 1, listed in tables 1 and 2, show the same characteristics and therefore must have similar compositions that result in said characteristics, i.e. the amount of resistant starch, or short chain amylose must be similar, since the samples of the instant invention state the sca is about 20 %, then it follows that the prior art must also contain sca of about 20 %. Wherein this falls within the applicant's range of 3-60%.

20. **Regarding claim 2**, Shi in '571 discloses the claimed invention, including hydrolysis rate being constant for at least 10 min, and less than 600 %/hr, as discussed below. The applicant determines the hydrolysis rate by measuring the amount of undigested starch at intervals of 15, 30, 45 and 60 minutes and calculating the digested portion of the starch. This data is plotted in Figures 1, 2, and 3. (pg 49 Applicant's specification) Shi measures the amount of glucose generated in the digestion reaction to give the digested portion of the starch at 20 min and 120 min. (lines 13-15 col. 7 '571) defines a rapidly digestible starch as being totally digested within 20 minutes. ( lines 52-



Art Unit: 1781

54 '571) Shi compares the amount of digested starch at 120 minutes with the amount at 20 minutes, to arrive at an estimate of the resistant starch. (lines 22-27 col. 7 '571)

In the Applicant's data, Shi's rapidly digestible starch corresponds to Fig 1 Kellogg's corn flakes, and Fig. 3, Sample set WS-57 1-4. Applicant in Table 2 lists the Ho%/h for sample set WS-57-1 from 800 to 1000. Shi in Tables 1 and 2 lists the amount of starch digested at 20 minutes ranging from 20 to 50 % of the total starch, and 120 minutes from 50 to 70 % digested. (Table 1 '571) Shi's slowly digestible starch fraction, in Table 1 is about 24 %/120 minutes or about 14.5 percent per hour. Comparable with the Applicant's values of 30 per cent per hour, Sample KS-1 Table 2, Applicant. However, as per the Applicant's Figs, 1-3 the curve is non-linear versus time, and thus, Shi's results are lower than the Applicants for digestion per hour. Looking at the 20 min values for Shi, and comparing to the Applicant's 15 and 30 minute values, it can be seen that the results for both methods are overlapping. (Table 1 and 2, '571, Figs. 1 and 2 Applicant)

21. **Regarding claim 4**, Shi discloses the claimed invention, as discussed above, including the DSC melting point of at least 70 deg. C. (lines 50-53 col. 4 '571)

22. **Regarding claims 7, 11, 12, 13, 14, 15 and 16**, said claims are dependent upon claim 18, and detail the process by which the food stuff in claim 18 is prepared. As discussed above, Shi teaches a resistant, gelatinized starch, (lines 6-9 col. 3, lines 46-48 col. 4, '571) a starch that is resistant to digestion in the small intestine, and passes into the large intestine, (line 13-15 col. 1 '571) a DSC melting point of at least about 90 deg. C (line 50-53 col. 4 '571), and digestibility being reduced to less than 50 % in two

Art Unit: 1781

hours. (lines 5-14 col. 1 '571) Unless the claims listed herein add some patentably distinct characterization to the foodstuff, then said foodstuff is anticipated by Shi. ('571)

**23. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Y-C. Shi, (6,890,571) in view of Y-C. Shi. (5,593,503)**

24. These are product by process claims, the determination of patentability in a product-by-process claim is based on the product itself, even though the claim may be limited and defined by the process. That is, the product in such a claim is unpatentable if it is the same as or obvious from the product of the prior art, even if the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985). A product-by-process limitation adds no patentable distinction to the claim, and is unpatentable if the claimed product is the same as a product of the prior art.

**25. Regarding claims 8 and 9, '571 and '503 disclose the claimed invention, as discussed above, including food products, cereal, bread, crackers, cookies, pasta, coated and fried foods, made using said modified starch. (Lines 40-45 col. 4, Claim 27 '503)**

26. '571 and '503 are analogous art in the both are concerned with the modification of starches to form a starch that is resistant to digestion in humans.

27. It would have been obvious to a person having ordinary skill in the art at the time of the invention to combine the teachings of '571 and '503 in order to produce a food product that is likely to be a factor in the prevention of diverticulosis and colon cancer.

Art Unit: 1781

(lines 30-32 col. 1 '503), and to produce a resistant starch that may contribute to reducing the risk of developing diabetes, or be useful in the treatment of hyperglycemia and obesity. (lines 36-40 '571)

28. **Regarding claim 10,** '571 and '503 disclose the claimed invention, as discussed above, including a discussion of increased organoleptic qualities such as crispiness, or preservative effects in those food products have good taste and appearance. (line 46, col. 9 '503, have acceptable mouthfeel and flavor, (line 67 col. 9, lines 30-31 col. 10, '503).

***Response to Amendment***

29. The applicant having cancelled claims 1 and 17 , the 35 USC § 112 rejections thereunto are withdrawn.

30. The applicant having added new claim 18, the 35 USC 112 rejections thereunto are instituted.

***Response to Arguments***

31. Applicant's arguments filed 11/18/10 have been fully considered but they are not persuasive.

32. Applicant states that the examiner was mistaken is in deducing the SCA content of Shi '571 samples 1A-1D, 2A and 2B is about 20 %, based on the similarity to the applicant's samples WS 57 1-4. WS 57. The applicant states that WS 57 lists a SCA of 0 %, and therefore the SCA of Shi must likewise be 0 %.

33. Examiner submits that the applicant's logical analysis is erroneous for the following reasons:

34. Shi's rapidly digestible starch samples,. samples 1A and 1C (table 1, '571)are similar to the applicant's sample set WS-57-1-4. Shi's slow digestible starch samples, samples 1B and 1D (table 2, '571) are similar to applicant's sample KS-1. Note KS-1 is listed as having 20 % SCA added.

35. The above statements are contained in paragraph 18, non-final rejection, 8/18/10, paragraph 6, final rejection 8/25/09, and paragraph 9, non-final rejection 11/25/08.

Art Unit: 1781

36. Examiner agrees that the applicant has not added any SCA to the cornstarch. However, Cornstarch is used by the applicant as an example of a slowly digestible starch, which the applicant states has desirable characteristics. (¶ 2, pg 1, specification)

37. Therefore, Shi's samples 1B and 1D, have the same characteristics as the applicant's samples KS-1 containing 20 % added SCA.

38. As to the Shi's sample having >90 % debranched starch, (lines 44-47, col. 3, '571) however, the applicant states debranching enzymes are used to produce SCA. (¶ 2, pg 6 specification)

39. Further arguments based upon the applicant's flawed analysis are moot, since the argument has been refuted.

40. Examiner submits that Shi's highly debranched starch does not preclude the products of Shi from having the same characteristics as the products of the applicant.

41. The determination of patentability in a product-by-process claim is based on the product itself, even though the claim may be limited and defined by the process. That is, the product in such a claim is unpatentable if it is the same as or obvious from the product of the prior art, even if the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985). A product-by-process limitation adds no patentable distinction to the claim, and is unpatentable if the claimed product is the same as a product of the prior art. Furthermore, the burden shifts to applicant, who has chosen to describe his *product* by using physical characteristics that the Office has no resources to compare with prior art products by manufacturing the

Art Unit: 1781

prior art product and making comparisons therewith. It is being assumed that since the reference has a similar product, made in a similar way, then the new feature being claimed must be present.

### ***Conclusion***

42. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

43. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY W. ANDERSON whose telephone number is (571)270-3734. The examiner can normally be reached on 7 am to 5 pm.

Art Unit: 1781

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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